UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

AMY ANDERSON,

Plaintiff,

v.

MERCK & CO., INC., et al.,

Defendants.

Case No. 22-cv-02991-JSW

ORDER GRANTING, IN PART, AND DENYING, IN PART, MOTION TO DISMISS, WITH LEAVE TO AMEND

Re: Dkt. No. 17

Now before the Court for consideration is the motion to dismiss filed by Defendants Merck & Co., Inc., Merck Sharp & Dohme Corp., Organon & Co., and Organon, LLC ("Defendants"). The Court has considered the parties' papers, relevant legal authority, and the record in this case. For the reasons that follow, the Court GRANTS, IN PART, AND DENIES, IN PART, the motion.

BACKGROUND

A. Preliminary Matters.

This is one of nine related cases pending before the Court that assert similar claims against Defendants. On October 12, 2022, the Court denied, in part, motions to dismiss filed in several of those cases and concluded it had specific jurisdiction over Defendants. *See Rosewolf v. Merck & Co., Inc.*, No. 22-cv-02072-JSW, 2022 WL 7127953 (N.D. Cal. Oct. 12, 2022) ("*Rosewolf II*"). Defendants state they move pursuant to Federal Rule of Civil Procedure 12(b)(2) to preserve their argument that the Court lacks personal jurisdiction over them but did not repeat their argument from earlier briefs. There are no material differences between the facts in this case and the facts in *Rosewolf II*, and for the reasons cited therein, the Court DENIES Defendants' motion to dismiss for lack of personal jurisdiction. 2022 WL 7127953, at *2-5.

In her opposition, Plaintiff Amy Anderson ("Anderson") conceded that her first claim for relief (strict liability – design defect) should be dismissed. She also conceded that her negligence claim should be dismissed, in part, to the extent it is premised on a manufacturing defect. (Opp. Br. at 5:26-6:3.) Pursuant to Anderson's voluntary dismissal, those claims are dismissed.

B. Factual Background.

Defendants manufacture and sell the brand-name drug "Singulair" and held patent rights in montelukast, Singulair's active ingredient, until the patent expired in August 2012. (Dkt. No. 1-1, Declaration of Julia Romano, ¶ 3 Ex. 1, Compl. ¶¶ 2, 29.) After the patent expired, other companies began to manufacture and sell generic monteluskat. (*Id.* ¶ 88.) Anderson alleges that monteluskat can cause neuropsychiatric injury by crossing the blood-brain-barriers. According to Anderson, Defendants knew monteluskat could cause these types of injuries but failed to warn of those risks and failed to maintain the accuracy and adequacy of Singulair's warning label. (*Id.* ¶¶ 34-87.) Anderson also alleges that Defendants "engaged in an extensive campaign to educate physicians in California about the alleged benefits of Singulair" but misrepresented its safety in that campaign. (*Id.* ¶ 21.)

On March 4, 2020, the Food and Drug Administration ("FDA") required Defendants to add a Black Box Warning to Singulair's label and required a new medication guide. That warning stated:

> Serious neuropsychiatric events have been reported in patients taking Singulair. These include:
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> agitation, aggressive behavior or hostility, anxiousness, depression, disorientation, disturbance in attention, dream abnormalities, dysphagia (stuttering), hallucinations, insomnia, irritability, memory impairment, obsessive-compulsive symptoms, restlessness, somnambulism, suicidal thoughts and behavior (including suicide), tic, and tremor …
>
> Psychiatric disorders: agitation including aggressive behavior or hostility, anxiousness, depression, disorientation, dream abnormalities, hallucinations, insomnia, irritability, restlessness, somnambulism, suicidal thinking and behavior (including suicide), tremor [*see Warnings and Precautions (5.4)*].

(Compl., ¶ 4 (emphasis in original)).

The warning also states that "the benefits of Singulair may not outweigh the risks," and the

FDA noted in a press release that "many patients and health care professionals are not fully aware of these risks." (*Id.*, ¶¶ 4, 6.) Anderson alleges that if she or her physician had known that Singulair "could cause [her] to suffer neuropsychiatric events, [the physician] would not have prescribed Singulair," and she would not have ingested it. (*Id.* ¶¶ 8, 12, 87.)

Anderson also alleges that:

> [w]ithin the period of any applicable statute of limitations, [she] could not have discovered through the exercise of reasonable diligence that Singulair caused a significantly increased risk of adverse neuropsychiatric events.
>
> [She] did not discover, and did not know of, facts that would have caused a reasonable person to suspect that [her] injuries were caused by Defendants' concealment and suppression of the fact that individuals who ingested Singulair were at significantly increased risk of developing neuropsychiatric events.
>
> [She] could not have reasonably discovered the true extent of Defendants' deception or suppression about Singulair's safety until the FDA required the Boxed Warning about the serious mental health side effects for Singulair and the advisement on the restriction of use of Singulair.

(*Id.* ¶¶ 95-96.)

Based on these and other allegations that the Court will address as necessary, Anderson asserts claims for: (1) strict liability – failure to warn; (2) negligence; (3) negligent misrepresentation; (4) breach of express warranty; and (5) breach of implied warranty.

ANALYSIS

A. Applicable Legal Standards.

When a defendant moves to dismiss for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6), the Court's inquiry generally "is limited to the allegations in the complaint, which are accepted as true and construed in the light most favorable to the plaintiff." *Lazy Y Ranch Ltd. v. Behrens*, 546 F.3d 580, 588 (9th Cir. 2008). Even under the liberal pleading standard of Federal Rule of Civil Procedure 8(a)(2), "a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (citing *Papasan v. Allain*, 478 U.S. 265, 286 (1986)).

Pursuant to *Twombly*, a plaintiff must not merely allege conduct that is conceivable but must instead allege "enough facts to state a claim to relief that is plausible on its face." *Id.* at 570. "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 556).

If the allegations are insufficient to state a claim, a court should grant leave to amend, unless amendment would be futile. *See, e.g., Reddy v. Litton Indus., Inc.*, 912 F.2d 291, 296 (9th Cir. 1990); *Cook, Perkiss & Liehe, Inc. v. N. Cal. Collection Serv., Inc.*, 911 F.2d 242, 246-47 (9th Cir. 1990).

B. Anderson Fails to Plead the Statute of Limitations Should be Tolled.

Defendants argue Anderson's claims are barred by the statute of limitations and that she fails to allege the limitations period should be tolled. "If the running of the statute is apparent on the face of the complaint, the defense may be raised by a motion to dismiss." *Jablon v. Dean Witter & Co.*, 614 F.2d 677, 682 (9th Cir. 1980). A court can grant a motion to dismiss on this basis "only if the assertions of the complaint, read with the required liberality, would not permit the plaintiff to prove that the statute was tolled." *Id.*

Defendants raised the same argument with respect to Plaintiff Rosewolf, and the Court granted Defendants' motion, with leave to amend. *Rosewolf v. Merck & Co., Inc.*, No. 22-cv-2072-JSW, 2022 WL 3372101, at *3-4 (N.D. Cal. Aug. 16, 2022) ("*Rosewolf I*"). Anderson alleges that she was prescribed Singulair between 2000 and 2020, and that "many or all" of her prescriptions were filled with branded Singulair, although she acknowledges some prescriptions may have been filed with generic Singulair. She also alleges the drug caused her to suffer neuropsychiatric events including depression, anxiety, panic disorder, stuttering, tics, and self-harm. (Compl. ¶ 8.) "[A] cause of action accrues at 'the time when the cause of action is complete with all of its elements.'" *Fox v. Ethicon Endo-Surgery, Inc.*, 35 Cal. 4th 797, 806 (2005) (quoting *Norgart v. Upjohn Co.*, 21 Cal. 4th 383, 397, (1999)). Anderson originally filed her complaint with two other named plaintiffs on March 4, 2022.

Anderson has not challenged Defendants' argument that a two-year statute of limitations

would be applicable to her claims and does not dispute that her claims would be barred unless the discovery rule applies. That rule delays accrual of a claim until "a plaintiff discovers or has reason to discover a cause of action," *i.e.* when they have a "reason at least to suspect a factual basis for its elements." *Id.* at 807; *see also Jolly v. Eli Lilly & Co.*, 44 Cal. 3d 1103, 1111 (1988) (a plaintiff will have reason to know of a claim when they have "notice or information of circumstances to put a reasonable person on inquiry"). In order to successfully plead tolling based on the discovery rule, Anderson must allege facts that show (1) how and when she discovered facts supporting the claim and (2) despite being reasonably diligent, she could not discover those facts earlier. *Fox*, 35 Cal. 4th at 808.

Anderson acknowledges that Singulair's label included warnings about neuropsychiatric events before 2020, although she alleges the warnings should have been stronger. (*See, e.g.,* Compl. ¶¶ 56, 61, 63, 66-67, 71-73.) Anderson alleges that she was put on notice of her claims *only* when the FDA issued the Black Box warning on March 3, 2020. (*Id.* ¶ 97.) If that is the date her claims actually accrued, her claims would be timely. Anderson alleges she took Singulair – or its generic equivalent – until 2020, which distinguishes the facts here from the facts in *Rosewolf I*, where there was a twelve year gap between the date the plaintiff last used the drug and the date the Black Box warning was issued. However, like the plaintiff in *Rosewolf I,* Anderson alleges she became symptomatic while ingesting Singulair.

Although Anderson provides no details about when her symptoms began, Defendants argue that because she uses the "®" mark following Singulair, she must have become symptomatic at some point between 2000 and 2012, when the only form of Singulair available was the branded version of the drug. The Court concludes it is reasonable to infer that Anderson's claims accrued at some point prior to March 4, 2020, a conclusion supported by the fact that Anderson expressly alleges the statute of limitations should be tolled.

Like the plaintiff in *Rosewolf I,* Anderson includes no facts to show when or how she learned about the Black Box label. She also not include any factual allegations about what she did prior to March 3, 2020 to investigate her symptoms. *See, e.g., Rosewolf I,* 2022 WL *3 (citing *Darringer v. Intuitive Surgical, Inc.*, No. 15-cv-00300-RMW, 2015 WL 6735333, at *2 (N.D. Cal.

Nov. 4, 2015)). Anderson relies, in part, on *Martin v. Medtronic, Inc,* No. 15-cv-00994-DAD-MJS, 2017 WL 825410, at *14 (E.D. Cal. Feb. 24, 2017) (citing *Retger v. Stryker Corp.*, 607 Fed. Appx. 732, 733 (9th Cir. 2015)). In that case, the plaintiff alleged he was injured by defendant's medical device. The plaintiff also alleged he received medical treatment for those injuries and alleged he relied on his doctor to inform him of the cause of the injury. The court concluded those allegations were sufficient to plead reasonable diligence. *Id.* Anderson argues that, like the plaintiff in *Martin*, she relied on her doctor to inform her of the causes of the symptoms he experienced and argues that neither she nor her physician were aware of the dangers Singulair posed.

With the exception of the year she stopped taking Singulair, Anderson's allegations are identical to the allegations in *Rosewolf I.* For the reasons articulated in that opinion, the Court finds Anderson's reliance on *Martin* and *Eidson v. Medtronic, Inc.* 40 F. Supp. 3d 1202 (N.D. Cal. 2014) unpersuasive. *Rosewolf I,* 2022 WL 3372101, at *3. Finally, "a plaintiff is 'charged with presumptive knowledge of an injury if they have information of circumstances to put [them] on inquiry *or* if they have the opportunity to obtain knowledge from sources open to [their] supervision.'" *Id.* (quoting *Fox*, 35 Cal. 4th at 807-08 (internal quotation marks omitted)). Anderson includes information about Singulair's earlier warning labels and also describes studies regarding the potential for neuropsychiatric events. Like Rosewolf, she fails to allege why that information would not have put her on inquiry notice of her claim. That is, she fails to provide facts to support her assertion that despite being reasonably diligent, she could not have discovered the facts giving rise to her claims earlier. *Fox*, 35 Cal. 4th at 808.

Accordingly, the Court concludes that Anderson's allegations are insufficient to plead around the statute of limitations, and it GRANTS Defendants' motion to dismiss.

C. The Court Cannot Conclude On this Record That Anderson's Negligence Claim Is Preempted.

Defendants also argue that Anderson's negligence claim is preempted. In light of the other pending cases and in order to evaluate whether it would be futile to grant Anderson leave to

amend, the Court addresses this argument.[1] The Supremacy Clause provides that federal law is "the supreme Law of the Land ..., any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI cl. 2. Therefore, "state laws that conflict with federal law are without effect." *Mut. Pharm. Co., Inc. v. Bartlett*, 570 U.S. 472, 479-80 (2013) (internal quotation and citation omitted) ("*Bartlett*"); *see also PLIVA, Inc. v. Mensing*, 564 U.S. 604, 617 (2011) ("[W]here state and federal law directly conflict, state law must give way.") ("*Mensing*"). Defendants argue it is impossible for them to comply with "both state and federal law requirements." *Id.* The Supreme Court has addressed the "demanding defense" of impossibility preemption in the context of prescription drugs in a trio of cases beginning with *Wyeth v. Levine*, 555 U.S. 555, 573 (2009).

In *Wyeth*, the Court held that a state law failure-to-warn claim against the manufacturer of a brand-name drug was not preempted because the defendant could modify its labelling without FDA approval. 555 U.S. at 568. The Court addressed the possibility that the FDA could have rejected a proposed change. It concluded, however, that it was not impossible for the defendant to comply with federal and state law "absent clear evidence that the FDA would not have approved a change to [the] label," which the defendant had not produced. *Id.* at 573.[2]

In *Mensing*, the Court held that state law tort claims against generic drug manufacturers based on a failure-to-warn theory were preempted because it was impossible for the generic manufacturers to comply with state laws, which required them to strengthen warnings on labels, and to comply with federal law, which precluded them from doing so. 564 U.S. at 624. The plaintiffs argued that the generic manufacturers could have asked for the FDA's assistance in

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[1] Anderson argues that discovery is necessary before the Court rules on this issue because "neither party is in a position to determine whether" her injuries were caused by branded Singulair or its generic equivalent. The Court is not persuaded, and it evaluates the allegations as drafted to determine whether Anderson pleaded herself out of a claim.

[2] The Supreme Court subsequently held that "the question of pre-emption is one for a judge to decide, not a jury" and that "'clear evidence' is evidence that shows the court that the drug manufacturer fully informed the FDA of the justifications for the warning required by state law and that the FDA, in turn, informed the drug manufacturer that the FDA would not approve a change to the drug's label to include that warning." *Merck Sharpe & Dohme Corp. v. Albrecht*, -- U.S. --, 139 S.Ct. 1668, 1672 (2019).

getting the brand-name manufacturer to change the label. *Id.* at 620. The Court, however, rejected that argument and explained that the "question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it." 564 U.S. at 620. Citing several other examples of asking a third-party to intervene to take action that would enable them to comply with state law, the Court concluded that if it accepted the plaintiffs' argument, it would render conflict preemption illusory. *Id.* at 620-21.

Finally, in *Bartlett*, the Supreme Court held that design defect claims against a generic drug manufacturer were preempted because the only way for the manufacturer to comply with state law would be to alter the label on its drug, which federal law precluded. 570 U.S. at 480, 486-87. The Court also rejected the reasoning by the Court of Appeals that the manufacturer could have complied with both laws by choosing not to sell the drug at all. It reasoned that a "stop-selling rationale [was] incompatible with [its] preemption jurisprudence," which "presume[s] that an actor seeking to satisfy both his federal and state-law obligations is not required to cease acting altogether in order to avoid liability." *Id.* at 488.

Anderson acknowledges that after the FDA approved Singulair, the Merck Defendants could not unilaterally alter the drug's design, but she argues her claims are based on what Defendants could have done prior to FDA approval. Defendants argue the Court should follow *Yates v. Ortho-McNeil-Janssen Pharmaceuticals,* which concluded pre-approval claims would be preempted. 808 F.3d 281, 293 (6th Cir. 2015). To date, the Sixth Circuit remains the only Circuit to have addressed this issue.

In *Yates*, the plaintiff suffered a stroke after using defendants' brand-name contraceptive drug and brought a strict liability design defect claim under New York law. *Id.* at 286. Defendants moved for summary judgment and argued the claim was preempted. That court rejected the argument that *Bartlett* and *Mensing* "extend[ed] to all design defect claims for both generic and brand-name drug manufacturer[s.]" *Id.* at 296. Rather, it recognized that "the federal statutes and regulations for brand-name and generic drugs are sometimes different" and that "brand-name and generic drugs may face different impossibility preemption results in some circumstances." *Id.* at 297.

The court then examined the defendants' duties under state law, which provided that a design defect existed when the product "was not reasonably safe because there was a substantial likelihood of harm and it was feasible to design the product in a safer manner." *Id.* at 297. Thus, state law allowed the defendants to avoid liability by choosing a safer design for the drug. *Id.* Second, it examined the duties imposed by federal law and agreed that federal law would not have precluded the defendants from creating and submitting a safer design to the FDA for approval. *Id.* at 299. However, the court found the plaintiff's argument about a pre-approval duty "too attenuated" and reasoned that "Defendants could not have complied with whatever pre-approval duty might exist without ultimately seeking the FDA's approval prior to marketing" the drug. *Id.* at 300. The court also concluded that the plaintiff's argument that the defendant could have designed a safer drug at the outset was analogous to the "stop-selling" argument the Supreme Court rejected in *Bartlett*. Therefore, the court concluded the plaintiffs' pre-approval claims were preempted. *Id.* at 300; *see also Evans v. Gilead Scis., Inc.*, No. 20-cv-00123-DKW-KJM, 2020 WL 5189995, at *9 (D. Hawai'i Aug. 31, 2020) (concluding pre-approval design defect claims preempted under Hawai'i law and adopting rationale that because defendant would be required to obtain FDA approval before selling drug it could not act "independently" of FDA); *Utts v. Bristol-Myers Squibb Co.*, 226 F. Supp. 3d 166, 185-86 (S.D.N.Y. 2016) (applying similar reasoning to conclude plaintiff's pre-approval design defect claim under California law, against brand-name manufacturer, was preempted).

Anderson argues the Court should decline to follow *Yates* and follow the reasoning in *Holley v. Gilead Sciences, Inc.*, 379 F. Supp. 3d 809 (N.D. Cal. 2019). *See also, e.g., Gaetano v. Gilead Scis., Inc.*, 529 F. Supp. 3d 333, 342-44 (D.N.J. 2021). In *Holley,* the plaintiffs (140 individuals from 31 states) asserted the defendant's drug, Truvada, caused bone and kidney damage and alleged the defendant could have, and did, designed a safer version of the drug by using a different ingredient. The defendant raised impossibility preemption as a defense on a motion to dismiss.

The court presumed the relevant state law duty was to have designed Truvada using a different compound, which also was eventually approved by the FDA. *Id.* at 814, 822. The

considered *Yates,* but it found "persuasive the weight of authority" from district courts outside the Sixth Circuit, which have found similar claims not preempted. *Id.* at 823-24. The court reasoned that the defendant failed to cite to any laws that precluded it from "designing a reasonably safe product prior to FDA approval," in the manner suggested by the plaintiff. *Id.* at 824 (citations and emphasis omitted). It rejected the Sixth Circuit's rationale that this theory would be "too attenuated," because all design defect claims require some hypothetical considerations. It reasoned it would not be "too attenuated to assume" the FDA would approve a safer version of a drug, especially when the plaintiff alleged it had done just that with defendant's subsequent drugs. *Id.* (citing *Guidry v. Janssen Pharm., Inc.*, 206 F. Supp. 3d 1187, 1208 (E.D. La. 2016)).

The court also concluded that *Yates* misstated *Bartlett's* "stop-selling" rationale. *Id.* at 825 (citing *Young v. Bristol-Myers Squibb Co.*, No. 4:16-cv-00108-DMB-JMV, 2017 WL 706320, at *8 (N.D. Miss. Feb. 22, 2017). "[T]he preapproval theory does not argue that a manufacturer should have stopped acting just that it should have acted differently," which would not run afoul of "the admonition in *Bartlett*." *Id.* (quoting *Young*, 2017 WL 706320, at *8). The plaintiffs asserted that the defendant should have offered the FDA a safer drug from the outset. Because the defendant had not presented evidence that it could not have done so and complied with both state and federal law, the court held that "[a]t this stage of the proceedings, Gilead has not satisfied the 'demanding' defense of impossibility preemption" for the design defect claims. *Id.*; *accord Gaetano*, 529 F. Supp. 3d at 343 (stating that a state law claim based on the assertion that a manufacturer should "act differently" at the "development stage, when the manufacturer is choosing among alternatives and its choice is not dictated by federal law" would not be preempted); *In re Zosavax (Zoster Vaccine Live) Prods. Liab. Litig.*, MDL No. 2848, 2021 WL 5235225, at *3-4 (E.D. Pa. 2021 Nov. 10, 2021) (noting split among district courts and following, *inter alia*, *Holley*). The Court finds the reasoning of the cases that have declined to follow *Yates* more persuasive. For the reasons articulated in *Holley* and based on the facts before the Court, it concludes Defendants have not demonstrated that Anderson's design defect claims are preempted. If Anderson is able to amend her claims to show they are not time barred, Defendants are free to renew this argument on a motion for summary judgment.

CONCLUSION

For the foregoing reasons, the Court GRANTS, IN PART, AND DENIES, IN PART, Defendants' motion to dismiss. Although Defendants asked the Court to dismiss Anderson's claims with prejudice because she declined their invitation to amend when they raised the statute of limitations issue, there is no evidence of bad faith, and the Court cannot say amendment would be futile. Accordingly, the Court GRANTS Anderson leave to file an amended complaint by December 12, 2022. Defendants shall answer or otherwise respond by January 6, 2023.

IT IS SO ORDERED.

Dated: November 21, 2022

JEFFREY S. WHITE
United States District Judge